

REMARKS

Applicants appreciate the Examiner's careful attention to this application.

These amendments and remarks are filed in response to the Office Action dated September 12, 2006, (the "Office Action"). This response is being filed with a petition for a three-month retroactive extension of time and the required fee. The Commissioner is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

I. STATUS OF THE CLAIMS

At the time of the Office Action, claim 41 has been cancelled. Claims 1-40 and 42-46 are pending in the application. Claims 1, 4-7, 10-21, 22-38, 40 and 46 have been withdrawn.

II. AMENDMENTS TO THE CLAIMS

Claims 2, 3, 9, 39, 42 and 43 are currently amended. Claim 47 is new. Applicants have taken care to exclude new matter from the claims, and Applicants allege that all amendments to the claims are fully supported by the specification.

Claim 2 is amended to replace the phrase "wherein a *cis*-acting elicitor responsive element consists of a nucleotide sequence of SEQ ID NO: 11" with "wherein ~~[[a]] at least one of the said two or more~~ *cis*-acting ~~elicitor-responsive~~ elements consists of a nucleotide sequence of SEQ ID NO: 11." This amendment is in response to the Examiner's suggested rephrasing of the claim in the Objection on page 2 of the Office Action. Applicants submit that this merely rephrases the claim, and introduces no new matter.

Claim 2 is further amended to include the new claim limitation "wherein induction of said local gene expression upon elicitor treatment or pathogen infection is at least 10-fold." This limitation is supported by the Specification on page 3, first full paragraph: "Preferably, the induction from the chimeric promoter upon pathogen attack

or elicitor treatment is at least about 10-fold higher, preferably 20-fold higher and particularly 30-fold higher than its activation, if any, by abiotic stress" (emphasis added). There is additional support in the Specification on page 30, Example 2: "Box D is a very strong elicitor-responsive element, a tetramer directing 10-fold elicitor-inducibility combined with a very high level of expression..." (emphasis added). Applicants submit the new claim limitation is supported by the Specification and introduces no new matter.

Claim 3 is amended into independent form. Amended Claim 3 includes all elements of the unamended Claim 2, plus all elements from the unamended Claim 3. As all elements of amended Claim 3 are found in previously submitted claims, Applicants submit that the amendment to Claim 3 introduces no new matter.

Claim 9 is amended to replace the term "said multimeric forms" with the term "said two or more *cis*-acting elements." The new term is supported in Claim 2, on which Claim 9 depends. Applicants submit the new claim limitation is supported by the disclosure of the Application and introduces no new matter.

Claim 39 is amended to include the element of "wherein induction of local gene expression upon elicitor treatment or pathogen infection is at least 10-fold." This limitation is supported by the Specification on page 3, first full paragraph: "Preferably, the induction from the chimeric promoter upon pathogen attack or elicitor treatment is at least about 10-fold higher, preferably 20-fold higher and particularly 30-fold higher than its activation, if any, by abiotic stress" (emphasis added). There is additional support in the Specification on page 30, Example 2: "Box D is a very strong elicitor-responsive element, a tetramer directing 10-fold elicitor-inducibility combined with a very high level of expression..." (emphasis added). Applicants submit the new claim limitation is supported by the Specification and introduces no new matter.

Claim 42 is amended as an independent claim. Claim 42 now incorporates all of the language of Claim 2, as Claim 2 read before the current amendments. As the inserted language in Claim 42 is identical to the language of Claim 2, as Claim 2 read before the current amendments, Applicants submit that the amendment introduces no new matter.

The Examiner rejected Claims 42 and 43, as these claims recite the limitation "said at least one *cis*-acting element." The Examiner pointed out that this term lacks

antecedent basis to the claims. In response, Applicants have amended the phrase "said at least one *cis*-acting elicitor responsive element" to "at least one of the said two or more *cis*-acting elements." Applicants submit this amendment introduces no new matter to the claims.

Claim 47 is new. New Claim 47 recites "The chimeric promoter according to claim 2, wherein induction of said local gene expression upon elicitor treatment or pathogen infection is at least 15-fold." The element of "induction of said local gene expression upon elicitor treatment or pathogen infection is at least 15-fold" is supported by the Specification on page 7, paragraph 2: "In a particularly preferred embodiment of the chimeric promoter of the invention the induction of gene expression upon elicitor treatment or pathogen infection is at least 15-fold." Applicants submit the new claim limitation is supported by the Specification and introduces no new matter.

For the reasons stated above, Applicants submit the amendments introduce no new matter to the claims, and respectfully request the Examiner enter the amendments.

III. OBJECTIONS TO THE CLAIMS

Claims 2 and 22 are objected to because of informalities. Applicants have amended claims 2 and 22 in accordance with the Examiner's recommendations. Applicants respectfully request reconsideration and withdrawal of the objections.

In Claim 2, the phrase "wherein a *cis*-acting elicitor responsive element consists of a nucleotide sequence of SEQ ID NO: 11" has been amended to "wherein [[a]] at least one of the said two or more *cis*-acting elicitor-responsive elements consists of a nucleotide sequence of SEQ ID NO: 11." This eliminates the objected language of "a *cis*-acting elicitor responsive element" and replaces it with the preferable language of "at least one of the said two or more *cis*-acting elements." Applicants respectfully request the Examiner withdraw the objection to Claim 2.

Claim 3 is objected to as being dependent upon a rejected base claim. Applicants have amended claim 3 accordingly as an independent claim, and respectfully request reconsideration and withdrawal of the objection.

IV. REJECTION OF CLAIMS 9 AND 42 – 45 AS INDEFINITE UNDER 35 U.S.C. §112

Claims 9 and 42 – 45 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner rejected Claim 9, as this claim recites the limitation "said multimeric forms." The Examiner pointed out that this term lacks an antecedent basis. In response, Applicants have amended Claim 9 to delete the rejected language. The objected language of "said multimeric forms" has been replaced with "said two or more *cis*-acting elements." The inserted language has antecedent basis in Claim 3, on which Claim 9 depends. As the rejected language has been replaced, Applicants respectfully request the Examiner reconsider and withdraw the rejection.

The Examiner rejected Claim 42, as this claim recites the limitation "said at least one *cis*-acting elicitor responsive element." The Examiner pointed out that this term lacks antecedent basis in the claims. In response, Applicants have amended the phrase "said at least one *cis*-acting elicitor responsive element" to "at least one of the said two or more *cis*-acting elements." The term "two or more *cis*-acting elements" has antecedent basis in Claim 2, on which Claim 42 depends. As the indefinite term now has a clear antecedent basis, Applicants respectfully request the Examiner reconsider and withdraw the rejection.

V. REJECTION OF CLAIMS 2, 8, AND 39 UNDER 35 U.S.C. § 102

Claims 2, 8 and 39 are rejected under 35 U.S.C. §102(b) as being anticipated by van de Locht *et al* (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document), (herein after "van de Locht"). Applicants respectfully traverse the rejection, as it is now moot in light of the current amendments.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.

1987). Claim 2 has been amended to include the element "wherein induction of said local gene expression upon elicitor treatment or pathogen infection is at least 10-fold" (emphasis added). This element is not found in the van de Locht article. The promoters constructed by van de Locht resulted in 3-fold to 9-fold induction of expression by elicitors. Van de Locht, Figures 5 and 6. The chimeric promoters claimed are limited to distinctly higher levels of gene induction. Applicants respectfully submit that a minimum of 10-fold induction of expression is patentably distinct from a 3 to 9-fold induction of expression.

Because van de Locht does not teach the new claim element of Claim 2, Applicants submit that van de Locht does not anticipate Claim 2. Claim 8 depends on Claim 2. If Claim 2 is not anticipated by van de Locht, then Claim 8 is not anticipated by van de Locht. Applicants respectfully request the Examiner reconsider and withdraw the rejections.

Claim 39 has been amended to include the element "wherein induction of local gene expression upon elicitor treatment or pathogen infection is at least 10-fold." As discussed in the previous paragraphs, the promoters of van de Locht do not show this level of activity. Because van de Locht does not teach the new claim element of Claim 39, Applicants submit that van de Locht does not anticipate Claim 39. Applicants respectfully request the Examiner reconsider and withdraw the rejection.

VI. REJECTION OF CLAIMS 2, 8, AND 39 UNDER 35 U.S.C. § 103

Claim 2, 8 and 39 are rejected under 35 U.S.C. §103(a) as being unpatentable over van de Locht in view of Pears and Williams (*Nucleic Acids Research*, 1988, Vol 16(17), pages 8467-84861) (hereinafter "Pears") and Searle *et al.*, *MCB*, 1985, Vol 5(6), pages 1480-1489) (hereinafter "Searle") further in view of Comai *et al.*, (*Plant Molecular Biology*, 1990, Vol 15(3), pages 373-381) (hereinafter "Comai"). Applicants respectfully traverse, as the rejection is moot in light of the current amendments, and there was no motivation to combine the cited references to produce the claimed invention.

A. THE CITED REFERENCES DO NOT TEACH ALL CLAIM LIMITATIONS

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royko*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Claims 2, 8 and 39 are currently amended to add an element not found in any of the cited references. As a result, Applicants submit the rejection is now moot.

Claim 2 has been amended to include the element "wherein induction of said local gene expression upon elicitor treatment or pathogen infection is at least 10-fold" (emphasis added). This element is not found in any of the cited references. Although van de Locht discloses promoters that induce expression in the presence of elicitors, the promoters constructed by Locht resulted in 3-fold to 9-fold induction of expression by elicitors. Van de Locht, Figures 5 and 6. The chimeric promoters claimed are limited to distinctly higher induction of gene expression. Applicants respectfully submit that a minimum of 10-fold induction of expression is patentably distinct from a 3 to 9-fold induction of expression.

Applicants further submit that the other cited references do not cure the infirmity of van de Locht, as they do not teach induction of local gene expression upon elicitor treatment or pathogen infection of at least 10-fold.

Because the cited references do not teach the new element of Claim 2, Applicants submit that they do not render obvious Claim 2. Claim 8 depends on Claim 2. If Claim 2 is not rendered obvious by the cited references, then Claim 8 is not rendered obvious by the cited references. Applicants respectfully request the Examiner reconsider and withdraw the rejections.

Claim 39 has been amended to include the element "wherein induction of local gene expression upon elicitor treatment or pathogen infection is at least 10-fold." As discussed in the previous paragraphs, the promoters taught in the cited references have distinctly lower activity. Because the cited references do not teach the new claim element of Claim 39, Applicants submit that the cited references do not render obvious

Claim 39. Applicants respectfully request the Examiner reconsider and withdraw the rejection.

B. THE CITED REFERENCES PROVIDE NO MOTIVATION TO COMBINE

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis). Applicants submit that it was not obvious to combine the cited references to form the claimed embodiments of the instant invention.

1. VAN DE LOCHT TEACHES AWAY FROM THE CLAIMS

Although van de Locht's promoters comprised SEQ ID NO: 11, van de Locht was not aware of the importance of this sequence. In fact, van de Locht clearly misses the importance of SEQ ID NO: 11 to elicitor-mediated expression. Van de Locht does not recognize the importance of the region from positions -47 to -52 to the functioning of SEQ ID NO: 11. Van de Locht expresses the belief that the region from -76 to -168 is critical to elicitor-mediated expression. As the claims are directed to the region from -76 to -47 that is SEQ ID NO: 11, van de Locht teaches away from the claims.

According to the teachings of van de Locht, PR2 will not function without the region from -76 to -168. "In contrast, further deletion of 60 bp between positions -168 and -108 (constructs pPR2-10 and pPR2-11) resulted in drastic decrease in the level of GUS activity." Van de Locht, page 2947, column 1. "These data show that the 116 bp between positions -168 and -52 of the PR2 promoter are necessary for elicitor-mediated expression of the gene." *Id.* "A regulatory sequence between positions -168 and -52 appears to be both necessary and sufficient to mediate this response [elicitor-mediated expression]." Van de Locht, page 2949, column 1. Based on the teaching of van de Locht, a person of ordinary skill would not think to use the region from -76 to -47, as this

region excludes part of the sequence van de Lochte teaches to be necessary for elicitor-mediated expression (-168 to -76), and includes a region van de Lochte teaches not to be necessary for elicitor-mediated expression (-52 to -47).

Furthermore, van de Lochte teaches that the region from position -168 to -108 is critical for elicitor-mediated expression, contrary to the principles underlying the instant invention. "Sequences between positions -168 and -108 appear to be critical for both elicitor-mediated and quantitative base-level GUS expression (compare pPR2-10 and pPR2-11)." *Id.* This sequence between positions -168 and -108 is not claimed. Based on the teachings of van de Lochte, a person of ordinary skill in the art would be led to believe that the claimed invention would not function, because SEQ ID NO: 11 lacks a region taught by van de Lochte to be critical for functionality.

As evidence that a skilled artisan would understand the article of van de Lochte to teach away from the claimed invention, Applicants submit the declaration of Dr. Inre Somssich.

The credentials and expertise of Dr. Somssich are described in paragraphs 1 through 3 of the Declaration. Dr. Somssich addresses the teachings of van de Lochte in paragraphs 6. Dr. Somssich points out that van de Lochte observed no elicitor-specific expression using promoters pPR2-11 and pPR2-12, both of which encompass SEQ ID NO: 11.

In paragraph 6, Dr. Somssich attests that the claimed invention performs surprisingly well when employed in synthetic promoters, and cites for further evidence the article of Rushton et al (*The Plant Cell* 14, 749 – 762, 2002). The Declaration further points out that tetrameric SEQ ID NO: 11 performs surprisingly well in conjunction with a minimal TATA box promoter. Dr. Somssich explains that the high levels of expression observed in tetrameric SEQ ID NO: 11 in conjunction with a minimal promoter would not be expected from the teachings of van de Lochte.

2. OTHER CITED REFERENCES TEACH AWAY FROM THE CLAIMS

As evidence that the cited references other than van de Leucht would not render the claimed invention obvious to one of ordinary skill in the art, Applicants submit the Declaration of Dr. Somssich.

In paragraph 7 of the Declaration, Dr. Somssich addresses the article by Pears. Dr. Somssich explains that Pears teaches away from the insertion of heterologous promoter sequences inserted into promoters, as Pears observed the insertion of a heterologous promoter into a promoter sequence did not mediate expression of the actin15 gene. The inserted sequence ("oligo L") was only effective when inserted into a homologous promoter. Moreover, Pears observed that an inserted sequence was only capable of mediating expression in a homologous gene when inserted into a position normally occupied by a very similar element. As a result, Pears teaches that chimeric promoters of the claimed invention are incapable of effectively mediating gene expression. Pears teaches away from the claimed invention.

Dr. Somssich addresses the article of Searle et al. in paragraph 8. Dr. Somssich points out that, although Searle observed that multimeric elements of a metal-responsive promoter conferred zinc-dependent expression that was absent in the monomer, other investigators have observed the opposite with other promoter elements. As a result, the findings of Searle would not render obvious the use of multimeric SEQ ID NO:11 to obtain conditional expression.

Dr. Somssich addresses the article of Comai et al. in paragraph 9. Dr. Somssich points out that, although Comai observed a twofold enhancement of expression levels when 35S promoter was joined with the *mas* promoter, Comai obtained conflicting results as to whether this approach works generally for all promoters. In fact, Comai observed negative results when some regions of the 35S promoter were used. Dr. Somssich points out that Odell et al. found that duplication of the same 35S promoter produced no enhancement of expression. As a result, there is no clear teaching in Comai that multimeric promoters can reliably enhance expression.

Applicants respectfully submit that, in light of the current amendments, the rejection is moot. Applicants further submit that a *prima facie* case of obvious has not been made, because the cited references teach away from the claimed invention, and provide no motivation to combine. Applicants respectfully request the Examiner reconsider and withdraw the rejections.

V. CONCLUDING REMARKS

For at least the reasons set forth above all currently pending claims are believed to be patentably distinct from the prior art. Applicants respectfully request the Examiner reconsider and withdraw all rejections, and issuance of a notice of allowance is respectfully requested.

As stated above, this response is being filed with a petition for a three-month retroactive extension of time and the required fee. The Commissioner is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

This submission is believed to be fully responsive to the Examiner's request. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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